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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,389	12/13/2005	J Michael Palmowski	0380-P03220US1	2535

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DANN, DORFMAN, HERRELL & SKILLMAN
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EXAMINER

BLUMEL, BENJAMIN P

ART UNIT	PAPER NUMBER
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1648

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04/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,389	Applicant(s) PALMOWSKI ET AL.	
	Examiner BENJAMIN P. BLUMEL	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 38-45 is/are pending in the application.
- 4a) Of the above claim(s) 3-6, 8, 9, 11, 12, 15-30, 38 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7,10,13,14,39-41 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/13/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 are examined on the merits. Claims 3-6, 8, 9, 11, 12, 15-30, 38 and 42 remain withdrawn from consideration.

Response to Arguments

Applicant's arguments filed 1/25/2010 have been fully considered but they are not persuasive. See responses below.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/478,623, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claim 1 recites, "...comprises an infectious,

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replication-deficient lentivirus engineered to comprise...”, however, application ‘623 does not provide any support for a lentivirus or engineered lentivirus that is infectious and replication-deficient. Therefore, the priority date of the examined claims is that of the PCT/GB2004/02512 filed on June 14, 2004.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 have been considered but are moot in view of the new ground(s) of rejection.

(New Rejection) Claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casimiro et al. (Journal of Virology, 2003), Hill et al. (US PGPub 2003/0138454) and Lewis et al. (Journal of Virology, 2001).

The claimed invention is drawn to a method of stimulating an immune response to an antigen in an individual by a heterologous prime-boost immunization protocol, the method comprising the steps of:

- i) administering to the individual a plasmid or other expression vector, which encodes said antigen to prime said immune response;
- ii) administering to the individual a lentivirus engineered to comprise exogenous nucleic acid encoding said antigen to boost the primed immune response. The exogenous nucleic acid encodes a pathogen-derived antigen, such as a lentiviral antigen. The claimed invention also includes a method of administering lentivirus particles, which encode said antigen, to an individual in order to boost a pre-existing immune response that was elicited by the administration of a nucleic acid also encoding said antigen. However, for purposes of examination, this alternative method involving the boosting of a pre-existing immune response is

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interpreted to be within the same scope as that of the prime/boost method of claim 1. The lentivirus is infectious but replication deficient.

Casimiro et al. teach the development of a prime-boost immunization protocol for inducing an immune response to HIV-1 *gag*. Casimiro et al. employed a heterologous prime boost system in which DNA encoding the gene is administered to macaques followed by infectious, replication deficient Adenovirus serotype 5 being administered that also encodes the *gag* gene. Casimiro et al. observed an increase in peripheral blood mononuclear cells after the boost administration relative to the priming dosage. Casimiro et al. also observed an increase in CD8⁺ T cells producing IFN- γ . However, Casimiro et al. do not teach the use of an infectious, replication deficient lentivirus engineered to encode an exogenous nucleic acid sequence of an antigen. *See pages 6306 and figures 6 and 7.*

Hill et al. teach the development of a heterologous prime-boost immunization protocol. Hill et al. use DNA or proteins of the antigen of interest (priming) followed by a replication deficient poxvirus that encodes the antigen of interest. One specific antigen that Hill et al. focus on is that of HIV envelope antigens. However, Hill et al. do not teach the use of an infectious, replication deficient lentivirus engineered to encode an exogenous nucleic acid sequence of an antigen. *See paragraphs 11, 12, 28, 30-33.*

Lewis et al. teach the development of an infectious, replication deficient lentivirus vector. *See page 9340.*

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Casimiro et al. and Hill et al. in order to use lentivirus that is infectious but can't replicate in a heterologous prime-boost method. One would have been motivated to do so, given

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the suggestion by Casimiro et al. and Hill et al. that the method be used to improve immune responses to HIV proteins via a heterologous prime-boost immunization protocol that relies on DNA encoding the protein and a replication deficient virus. There would have been a reasonable expectation of success, given the knowledge that recombinant replication deficient, infectious lentiviruses can be generated and can express exogenous proteins, such as GFP, as taught by Lewis et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/
Examiner
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